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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,710	09/05/2000	Suman Preet Singh Khanuja	056859/0107	8287

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WASHINGTON, DC 20007

EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/655,710

Applicant(s)

KHANUJA ET AL.

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,5,6,9,10 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,9,10 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25, 2003 has been entered.
2. Claims 2, 4, 7, 8, 11-26, and 28-48 have been cancelled.
3. Claims 1, 3, 5, 6, 9, 10, and 27 are currently pending.

### ***Claim Objections***

4. Claim 1 is objected to because of the following informalities: "licorice" is misspelled as "liqouricie." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "licorice preparation" and "dried root" do not have proper antecedent basis in the parent claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 5 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,939,050 for the reasons set forth in the previous Office action.

Applicant has amended the claims to recite that the bioenhancer is selected from licorice, glycyrrhizic acid or glycyrrhizin. Licorice is the common name for *G. glabra* root. In addition, glycyrrhizic acid and glycyrrhizin are both found in *G. glabra* extract; thus, *G. glabra* extract is considered to be a composition comprising glycyrrhizic acid and glycyrrhizin.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach the claimed invention because the reference teaches using the extract in anti-microbial effective amounts. Applicant uses 1ug/ml and 25 ug/ml of *G. glabra* extract in their specification. Therefore, applicant has functionally defined these amounts as the effective amount of *G. glabra* extract. The reference teaches using *G. glabra* extracts in these amounts. Therefore, the reference amounts meet what applicant has defined as the effective amount.

Applicant also argues that the reference does not teach using glycyrrhizin. However, applicant's claim 1 states that the composition comprises a bioenhancer is selected from licorice, glycyrrhizic acid or glycyrrhizin. The reference specifically states that the *G. glabra* extract is licorice and contains glycyrrhizic acid (see column 4, lines 34-42). In addition, glycyrrhizin is a

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component naturally found in *G. glabra*; therefore, the reference extract would contain glycyrrhizin. Applicant also argues that there would be additional components in the “crude” extract used in the reference. However, since applicant’s claims use the transitional phrase “comprising,” additional elements can be present in the composition. Applicant’s claims do not specify that the glycyrrhizic acid and glycyrrhizin are purified or isolated from the starting source.

Applicant also argues that it is not possible to determine the ratio of *G. glabra* to “Agent B” in the reference; thus, the claim 6 is not anticipated. However, claim 6 is not included in this rejection.

In response to applicant's argument that the reference uses the composition for a different purpose, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The reference composition is considered to be the same as the claimed composition for the reasons discussed above; therefore, there is no structural difference that patentably distinguishes the claimed invention from the prior art.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 5, 6, 9, 10, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,939,050, The Merck Index (Budavari et al. (eds) (1989), 11<sup>th</sup> edition, Merck & CO., Inc: New Jersey, entry numbers 2315, 6273, and 6617) and US Pat. No. 5,478,829 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claims are not obvious because applicant is not using the *G. glabra* extracts as antibacterial agents. However, the prior art teaches using *G. glabra* extracts in amounts that meet what applicant has defined as the effective amounts. Therefore, it is considered obvious to use these amounts for the reasons of record. Simply because the prior art uses a composition for a different purpose does not make a composition allowable. Since applicant is claiming a composition rather than a method of use, the composition is still considered to be obvious based on the reasons of record.

In addition, applicant argues optimization of the ingredient amounts would yield a *G. glabra* product where the *G. glabra* has anti-bacterial properties. However, the prior art teaches using amounts of *G. glabra* that meet applicant's definition of effective amount. It is considered to be obvious for a person of ordinary skill to add additional antibacterial agents to the amount of *G. glabra* used in the prior art that would meet the limitations set forth in applicant's claim 6.


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8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Susan Coe, Examiner  
February 12, 2004